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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,918	01/02/2001	Zhi-Qiang Xia	WSUR116430	7095

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EXAMINER
PAK, YONG D

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,918	Applicant(s) XIA ET AL.	
	Examiner Yong Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *3-5 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-10,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 & 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a 371 of PCT/US99/08975. The amendment filed January 28, 2003, canceling claims 11-17 and 22-23, has been entered.

Claims 1-10 and 18-21 are pending.

Election/Restrictions

Applicant's election with traverse of Group I drawn to SEQ ID NO:1, a nucleic acid sequence encoding a secoisolariciresinol dehydrogenase from *Forsythia intermedia*, in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the nucleic acid sequences of SEQ ID NO:1, 3, 5, 7 and 9 encode the same type of protein and have similar nucleic acid sequences. This is not found persuasive because as applicants have stated, the nucleic acid sequences encode a protein with different physical and chemical properties, such as substrate specificity or pH optimum.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-5 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claim Objections

Claims 1, 8-10, 18 and 20-21 are objected for being drawn to non-elected products, SEQ ID NOs: 3-10 and secoisolariciresinol dehydrogenase from various sources.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is drawn to DNA molecules comprising 15 nucleotides that hybridize to the DNA of SEQ ID NO:1. A description of about 1% of the whole structure of DNA encoding SEQ ID NO:1 amount to insufficient description of the structure of the DNA molecule in this claim. Therefore, these claims are drawn to a genus of DNA encoding polypeptides with any activity or unknown activity, with no limitation on structure. The specification also does not describe the function of all the polypeptide sequences encoded by the polynucleotides derived or modified from SEQ ID NO:1 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, the specification fails to describe any identifying characteristics or functionality other than comprising of 15 nucleotides.

Given this lack of the description of the representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claim 10.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the dehydrobenase of SEQ ID NO:2, does not reasonably provide enablement for DNA molecules comprising 15 nucleotides hybridizing to the DNA of SEQ ID NO:1 having unknown activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

This claim encompasses polynucleotides with no structure because 15 nucleotides, which is less than 1% of the whole structure of DNA encoding SEQ ID NO:2, amounts to very little structural limitation. Applicants do not teach which 15

nucleotides of SEQ ID NO:1 must be present in a DNA molecule for it to encode a functional secoisolariciresinol dehydrogenase. Also, it is unpredictable whether a DNA fragment comprising 15 bases encodes a functional enzyme. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification, which places weak limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the secoisolariciresinol dehydrogenase structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

In the state of the art, the function of a polypeptide is unpredictable from its structure and the functionality of a polypeptide must be known in order to use the

polypeptide. Therefore, the specification does not teach how to use polypeptides with unknown function.

Therefore, one of ordinary skill would require guidance in order to make and use DNA comprising of 15 that hybridizes to SEQ ID NO:1 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Herbers et al.

Herbers et al. (form PTO-892) teach a nucleic acid molecule that comprises of 15 bases and hybridizes to SEQ ID NO:1 under the conditions specified in claim 10. Therefore, the teaching of Herbers et al. anticipates claim 10.

Claims 1-2, 6-10, 18, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Davin et al.

Davin et al. (form PTO-1449) teach that a secoisolariciresinol dehydrogenase has been purified and that cloning of this gene has been undertaken (see abstract). Nucleic acid fragments used to start the cloning of this gene and various other Forsythia genes hybridizes to SEQ ID NO:1 and the procedure comprises of vectors and host

cells comprising these fragments. Therefore, the teaching of Davin et al. anticipates claims 1-2, 6-10 and 18-21.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

March 4, 2003

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